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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,923	06/21/2007	Daniel J. Rader	AGP-002	5393

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GOODWIN PROCTER LLP
PATENT ADMINISTRATOR
53 STATE STREET
EXCHANGE PLACE
BOSTON, MA 02109-2881

EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
07/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PatentBos@goodwinprocter.com
hmcpeake@goodwinprocter.com
glenn.williams@goodwinprocter.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,923	RADER, DANIEL J.	
	Examiner	Art Unit	
	KEVIN WEDDINGTON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,9,16,18 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,9,16,18 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-14-2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-4, 6, 8, 9, 16, 18 and 26-28 are presented for examination.

Applicant's amendment, information disclosure, and declaration filed April 14, 2010 have been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph (Written Description) as set forth in the previous Office action dated October 21, 2009 at pages 2-4 as applied to claims 1, 3-18, 20, 24 and 25 is hereby withdrawn because of applicant's amendment.

Accordingly, the rejection made under 35 USC 102(b) as being anticipated by Biller et al. (5,739,135) as set forth in the previous Office action dated October 21, 2009 at pages 4-5 as applied to claims 1-4, 6-8, 14, 15, 17, 19 and 22 is hereby withdrawn because the applicant amended the claims to recite a specific MTP inhibitor.

Accordingly, the rejection made under 35 USC 103(a) as being obvious over Biller et al. (5,739,135) in view of Dow (6,194,454 B1) as set forth in the previous Office action dated October 21, 2009 at pages 7-8 as applied to claims 9-13, 17, 24 and 25 is hereby withdrawn because the applicant amended the claims and cancelled the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, 16 and 18 are again rejected under 35 U.S.C. 102(b) as being anticipated by Gregg et al. (5,883,109) of record, for reason of record as set forth in the

previous Office action dated October 21, 2009 at pages 5-6 as applied to claims 1-8, 14-16, and 18-23.

Applicant's remarks regarding the independent claim 1 has been amended to include limitations of claim 13 which do not stand rejected by the prior art, Gregg et al., are not persuasive since claim 1 do not recite all the limitations that were disclosed in claim 13. Claim 13 disclosed five doses levels and applicant's claim 1 only recite three doses levels. Note in the prior art in column 23, lines 50-54 showed the combination can be administered to the subject in a single or divided doses or one to four times daily. It is also noted to be advisable to start a patient on a low dose combination and work up gradually to a high dose combination.

Again, the cited prior art taught every limitation of the applicant's instant method for treating a subject suffering from hyperlipidemia or hypercholesterolemia, and inhibiting MTP with amounts administered in intervals of one to four time daily and further comprising a second agent.

The rejection made under 35 USC 102(b) is adhered to.

Claims 1-4, 6, 8, 16 and 18 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregg et al. (5,883,109) in view of Rosenblum et al. (5,767,115).

Gregg et al. teach the use of a MTP inhibitor, 9-[4-[-[[2-(2,2,2-trifluoroethoxy)benzoyl]amino]-1-piperidinyl]butyl-N-(2,2,2-trifluoroethyl)-9H-flourene-9-carboxamide, is effective in treating hyperlipidemia and hypercholesterolemia. Note column 21, lines 25-67 to column 22, lines 1-63 shows the other cholesterol lowering agents can be administered with the primary active agent. Note the administration of the MTP inhibitor alone or in combination with another cholesterol lowering agent can be oral with a single or divided doses or one to four times daily.

The instant invention differs from the cited reference in that the cited reference does not teach a fifth dose level is administered with the previous one to four daily administration. However, one skilled in the art would have assumed that addition of a fifth administration is obvious since it is advisable to start a patient on a low dose and work up gradually to a high dose (the fifth dose in a high dose level) in the absence of evidence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not teach the applicant's preferred other cholesterol lowering agent, ezetimibe. However, the secondary reference, Rosenblum et al., teaches ezetimibe as a well-known agent for lowering cholesterol levels. Clearly, one skilled in the art would have assumed the combination of two individual agents, each well-known to lowering cholesterol levels, into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 9 and 26-28 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN WEDDINGTON
Primary Examiner
Art Unit 1614

/KEVIN WEDDINGTON/
Primary Examiner, Art Unit 1614